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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/663,709 | 09/18/2000 | Hiroiyuki Fujita | 001200 | 4404 |

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07/16/2002

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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 07/16/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,709

Applicant(s)

FUJITA, HIROYUKI

Examiner

Anish Gupta

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment and the substitute specification, filed 2-22-02, has been entered. The amendment amended claims 1, 2, 5 and 6. Claims 1-10 are pending in this application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5 and 6 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous office action and the reasons set forth below.

Claim 5 and 6 still recite "a residue." However it is unclear what part of the fish meat constitute "a residue." In their response, Applicants did not address this limitation since a definition of "a residue" was not furnished.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Masayasu for the reasons set forth in the previous office action and the reasons set forth below

5. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Suetsuna for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a angiotensin converting enzyme inhibitor.

For all of the rejections, Applicants argue that none of the reference cited teach a portion of peptide having a molecular weight of at least 5000 is more than 10% by weight. This is beyond the scope of the claimed invention. Applicants have submitted a declaration by Dr. Fujita that demonstrate that the compositions disclosed by the reference have peptides having a molecular weight of at least 5000 more than 10% by weight. The Declaration by Dr. Fujita performs the same preparation methodology used in the reference to make the composition and demonstrates that the methodology did not result in a composition containing peptides having peptides of molecular weight of 5000 as encompassed by the claims.

Applicant's arguments filed 2-22-02 have been fully considered but they are not persuasive.

For the references of Masayasu (JP04139196), the declaration states that the methodology disclosed on page 681 was used and peptides having a molecular weight of 5000 was 25%. Similarly, for Suetsuna applicants state that the method of column 5, lines 12-17 was used and yielded peptide having molecular weight of greater than 5000. However, the both references states that the hydrolyzed solution is concentrated by centrifugal separation and subsequently purified by high performance liquid chromatography (see abstracts of both references). The example in the declaration does not utilize HPLC to purify the centrifuged composition. Thus the example in the declaration do not clearly reflect the methodology disclosed the reference. For these reasons and the reasons set forth in the previous office action, this rejection has been maintained.

6. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al. for the reasons set forth in the previous office action and the reasons set forth below.

For this reference, the declaration states that the procedure described in "Digestion of dried bonito" was used and resulted in various % content of Pepsin, trypsin and chymotrypsin. This sample, as with the Masayasu reference, seems to overlook the purification procedure outlined in the Materials and Methods section. Note that this section specifically states that the digestion supernatant was subject to column chromatography and HPLC. Further the reference states that "when the obtained peptide was not pure after three HPLC steps, the peptide was further purified on a ODS column. . ." Thus, the reference teach a composition containing pure peptide. For these reasons and the reasons set forth in the previous office action, the reference still anticipates the claimed invention

7. The rejection of claims 1-10 rejected under 35 U.S.C. 102(b) as being anticipated by Yoshikawa et al. (US 5,369,015) is hereby withdrawn.

NEW GROUNDS FOR REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite that the peptide ingredient has a “molecular weight of at least 5000 is at most 10% by weight with respect to a solid portion of the composition.”

However, it is unclear what portion of the composition constitutes the “solid portion.” The claim does not make a distinction that there is a solid and or non-solid portion to the composition.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

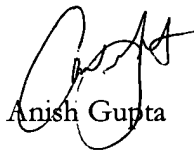
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



July 15, 2002

Chris Low
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